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United States General Accounting Office
Washington, DC 20548

June 22, 2001

The Honorable Christopher J. Dodd
The Honorable Rick Santorum
United States Senate

The Honorable Virgil H. Goode, Jr.
The Honorable Joseph R. Pitts
The Honorable Christopher H. Smith
House of Representatives

Subject: Federal Agencies Generally Meet Requirements for Disclosure and Review of Financial Interests Related to Lyme Disease

Some Lyme disease patients and some of their organizations are concerned that federal employees and advisors involved in decisions regarding the funding of Lyme disease research and the approval of products related to Lyme disease may have financial interests in firms that could benefit from these decisions. Specifically, the patients and their organizations are concerned that these interests may affect the Centers for Disease Control and Prevention's (CDC) recommendations about the diagnosis, treatment, and prevention of Lyme disease, the National Institutes of Health's (NIH) funding of research on the disease, and the Food and Drug Administration's (FDA) approval of products related to Lyme disease. For example, they are concerned that agency officials and advisors involved in FDA's decision to approve an application to license a Lyme disease vaccine may have had financial interests in firms that would benefit from its licensure.

Federal requirements concerning financial conflicts of interest at CDC, NIH, and FDA are set by laws and regulations, which are implemented in accordance with the policies of each agency and the Office of Government Ethics (OGE).[1] These requirements generally apply to all agency employees, including those special government employees (SGE) appointed to federal advisory committees.[2]

You requested that we review (1) the financial interests that CDC, NIH, and FDA employees and members of advisory committees working on Lyme disease have reported and (2) how these agencies addressed any potential conflicts of interest identified in those reports.

[1]OGE, an executive branch agency, was established by the Ethics in Government Act of 1978 (P.L. 95-521), and established as a separate agency in 1988.
[2]SGEs are temporary or intermittent employees who perform services with or without compensation. SGEs serving on advisory committees may advise the agency on actions to be taken, but program officials make any final decisions.

To respond to this request, we interviewed agency officials and reviewed all financial disclosure forms of relevant CDC, NIH, and FDA employees and SGEs working on Lyme disease from fiscal years 1996 through 2000. For purposes of this review, "employees" refers to those permanent agency employees working on Lyme disease in decision-making roles. We confined our review to specific divisions/institutes with Lyme disease activities: CDC's Division of Vector Borne Infectious Diseases; NIH's National Institute of Allergy and Infectious Diseases; and FDA's Center for Biologics Evaluation and Research. "SGEs" refers to those temporary employees serving on advisory committees related to Lyme disease. We included only the SGE voting members attending specific advisory committee meetings. Our review included an examination of financial interests, as disclosed on the forms, including holdings, travel reimbursements, consulting, and income from patents to determine if these pose potential conflicts.[3] We recorded the number and types of holdings, but not specific dollar values, as OGE does not require that they be included in the forms. In addition to disclosure forms, we examined agency travel records. We identified patents that name CDC, NIH, and FDA employees currently working on Lyme disease through a review of public patent records, and we recorded the income received from those patents. We reviewed both the federal and agency-specific policies, laws, and regulations used by CDC, NIH, and FDA to monitor and control the influence of outside interests on decision-making. We also reviewed reports issued by OGE of each agency's general compliance with federal ethics requirements. We did not independently obtain information on the financial interests or travel of the relevant employees and SGEs. Our work was conducted in accordance with generally accepted government auditing standards from June 2000 through May 2001.

In summary, we found that CDC, NIH, and FDA have generally met the requirements for disclosure and review of financial interests related to Lyme disease. Employees and SGEs working on Lyme disease-related activities have reported financial holdings in, and arrangements with, health sector firms, travel paid for by health sector firms, and patents related to Lyme disease. In general, more SGEs, whose primary employment is elsewhere, reported financial interests than did employees. Employees of FDA reported no financial interests in health sector firms. As required, the agencies' officials have reviewed and cleared the financial interests of employees and SGEs working on Lyme disease-related activities. Program officials and agency officials reviewed the interests of the employees and determined that they did not present conflicts. However, program officials determined that many of the interests of SGEs who served as advisors did pose potential conflicts. In every case where a potential conflict was identified, the program officials submitted a formal waiver request, in accordance with a statutory provision that allows individuals to serve if the need for their services outweighs the potential for a conflict of interest. In each instance, agency officials granted the waivers. OGE has reviewed the activities of the agencies' ethics offices and said that they generally comply with applicable statutes and regulations. OGE's reviews were general and did not specifically address conflicts of interest related to Lyme disease.

We provided a draft of this letter to the Department of Health and Human Services for review. The department stated that it had no comments.

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[33]We considered interests in a broad range of health sector firms as potentially posing conflicts for CDC and NIH employees and NIH SGEs because CDC and NIH research on Lyme disease could affect many pharmaceutical and biotechnology firms. The reported interests of FDA employees and FDA and CDC SGEs were considered potentially conflicting if they related to a for-profit health sector company that is currently regulated as a vaccine company by FDA, because these individuals had responsibilities related only to the Lyme disease vaccine.

Background

Potential conflicts of interest arise in all government agencies. To limit the potential conflicts arising from financial relationships, OGE issues regulations regarding the financial interests of employees and SGEs of the executive branch in accordance with various laws dealing with conflicts of interest and agencies may establish policies to implement those requirements. Under the Ethics in Government Act, executive branch employees and SGEs are generally required to file a financial disclosure report with their agency. The disclosure process is intended to make agency officials aware of the potential conflicts of the employees and SGEs. Potential conflicts of interest may be particularly likely to occur among SGEs, whose primary employment is elsewhere, and very likely related to the expertise qualifying them to be an SGE. All relevant financial interests are to be reported, which could include financial holdings, salaries, fees, honoraria, outside positions, income from investments, or other financial agreements, travel reimbursement, and royalties from personally held patents.[4] See enclosure I for more information on financial disclosure policies relevant to employees and SGEs.

Agency officials are required to review each financial disclosure report to determine whether a financial interest constitutes a potential conflict. A disqualifying interest may include significant financial holdings by the employees or SGEs, or their spouse, minor child, or general partner. If such an interest is identified, the employees or SGEs are prohibited from participating in the relevant matter, unless they receive a waiver. If no waiver is granted, they must recuse themselves from the matter or divest themselves of their financial interest.

SGEs serving on advisory committees may be eligible for a waiver if a determination is made that the potential for a conflict is outweighed by the need for the services of the SGE advisor.[5] Program officials request the waiver, which agency officials may choose to grant. For the advisory committees relevant to Lyme Disease, CDC's Executive Secretary of the Advisory Committee on Immunization Practices requests a waiver from CDC's Deputy Ethics Counselor; NIH National Institute of Allergy and Infectious Diseases' Director of Extramural Activities requests a waiver from the Institute's Deputy Ethics Counselor; and FDA's Chief of Advisors and Consultant Staff requests a waiver from FDA's Senior Associate Commissioner. As a condition of the waiver, CDC and FDA must, and NIH may, publicly disclose, at the beginning of each committee meeting, the financial interests of advisors for whom waivers have been granted.

In addition to financial holdings, conflicts of interest could potentially arise when the agency, on behalf of its federal employees, accepts payment for travel from nonfederal sources. Agencies are authorized, within certain parameters, to accept such payments.[6] This travel must relate to the employee's official duties, and typically involves the employee's participation in meetings or conferences. Payments may be in-kind[7] or provided through other means, such as reimbursement of expenses. It is the responsibility of agency officials to determine whether the travel payment represents a conflict of interest.

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[4]Those who file financial disclosure forms do not have to report certain minimal sources of income, such as earned income with a value of less than $200.

[5]Other employees may be eligible for a waiver if the potential conflict is determined to be unlikely to affect the integrity of the employees' services to the government.

[6]The payments may include transportation, food, lodging, and related expenses, such as taxi fare (see 31 U.S.C. 1353; 41 C.F.R. pt. 304-1).

[7]A payment is in-kind when it involves something other than cash, such as an airplane ticket.

The payment of royalties to a federal employee for an invention developed in a federal laboratory is another type of financial interest subject to certain rules.[8] If an invention is developed in a federal laboratory, the federal agency normally retains the title to the invention and can license it to others who may then commercialize it. If the agency receives royalty income from inventions licensed to companies that commercialize them, the royalties are distributed according to statute. When federal employees are named as inventors on federally-held patents, they may receive income derived from these royalties. Inventors receive, through their agencies, the first $2,000 in royalties and at least 15 percent of receipts thereafter, up to $150,000 annually per person.[9] The remaining royalties are allocated to either the laboratory or agency from which the patent originated, or the U.S. Treasury. The employee-inventor is permitted to engage in commercialization activities if they are consistent with agency conflict-of-interest regulations and standards of conduct.

Employees and SGEs Working on Lyme Disease Have Reported Interests in Health Sector Firms

Eight of the 17 (47 percent) relevant CDC and NIH employees whose forms we reviewed reported financial interests in health sector firms--but not necessarily firms developing or producing Lyme disease products--and 45 of the 87 (52 percent) SGEs working with CDC, NIH, and FDA on the disease reported such interests. (See table 1.) FDA employees reported no financial interests in health sector firms; however, one employee received patent royalties that were unrelated to Lyme disease. Most of the health-related financial interests that employees and SGEs disclosed were investments, consulting and advising fees, speaking and writing honoraria, and patents. In addition, SGEs also disclosed interests related to contracts and grants, employment, and expert witness fees. Requests for travel reimbursement were primarily to attend professional meetings and monitor progress on cooperative agreements with other organizations.

Table 1: Financial Interests Summary, Fiscal Years 1996 Through 2000

Agency and type of employee		Financial holdings and arrangements in/with health sector firms?	Travel paid for by health sector firms?	Royalty income from personally held patents?	Named in federal patents (reported in public records)?	Royalty income from federal patents?
CDC	employee	Yes	Yes	No	Yes	No
	SGE	Yes	N/A	Yes	N/A	N/A
NIH	employee	Yes	Yes	No	Yes	Yes
	SGE	Yes	N/A	Yes	N/A	N/A
FDA	employee	No	No	No	Yes	Yes
	SGE	Yes	N/A	Yes	N/A	N/A

SGE = special government employee
N/A = not applicable
Source: GAO analysis of CDC, NIH, and FDA confidential financial disclosure forms.

[8]These payments are governed by the Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480), as amended, which was enacted to encourage the commercial use of technologies developed in the federal laboratory system.
[9]Any amount above that requires presidential approval (15 U.S.C. 3710c(a)(3)).

CDC Employees and SGEs Working on Lyme Disease

CDC employees reported financial interests in health sector firms. CDC provided us with 52 of the expected 57 annual confidential financial disclosure forms from 12 employees working on Lyme disease, covering fiscal years 1996 through 2000. Six of the 12 employees reported at least one interest in a health sector firm on at least one of their yearly financial disclosure forms. Further, CDC provided us with 19 forms documenting the request and approval of travel expenses from nonfederal sources for personnel working on Lyme disease. Eight of these trips were paid for by health sector firms, generally in connection with federally approved Cooperative Research and Development Agreement research under the Stevenson-Wydler Technology Innovation Act of 1980, as amended. Academic or other nonprofit institutions paid for the other 11 trips.

CDC employees working on Lyme disease are listed on two Lyme disease-related patents(1) a patent filed by BioMeriuex, Inc., that resulted from Cooperative Research and Development Agreement work to develop a chemical potentially useful in developing diagnostic methods and (2) a 1993 joint patent between CDC and the SmithKline Beecham Corporation[10] on compositions useful in the diagnosis and prevention of Lyme disease. CDC program officials stated that no CDC-owned Lyme disease patents have been licensed. CDC has not distributed any royalty payments to employees working on Lyme disease. In addition, CDC employees working on Lyme disease did not report any royalty income from nonfederal patents related to Lyme disease.

CDC SGEs also reported financial interests in health sector firms. CDC provided us with all 12 confidential financial disclosure forms from the 12 SGEs serving at the 1998 meeting of the Advisory Committee on Immunization Practices where the Lyme disease vaccine was discussed. Six of the 12 SGEs reported at least 1 interest related to a vaccine firm.

NIH Employees and SGEs Working on Lyme Disease

NIH employees reported financial interests in health sector firms. NIH provided us with 20 of the expected 23 annual financial disclosure forms from five employees working on Lyme disease from 1996 through 2000. On those forms that we received, two of the five employees reported at least one health sector interest. One of these two employees reported a single health sector investment, while the other reported numerous interests.

There were also several instances of travel expenses incurred by NIH employees paid to NIH by nonfederal organizations. NIH provided us with 45 documented instances of payment of NIH employee travel expenses from nonfederal sources for employees working on Lyme disease. Of these, 41 were to attend or speak at conferences and seminars, and the remaining 4 were to attend other meetings. Three of the trips were paid for by for-profit firms and 41 by nonprofit organizations. One form, for travel reimbursement to speak at a conference, did not indicate the sponsor.

There are six patents related to Lyme disease on which NIH employees working on Lyme disease are listed as inventors. The patents relate to the laboratory detection of *Borrelia burgdorferi,* the organism that causes Lyme disease. Four of those patents are assigned to the Department of Health and Human Services. Certain of these patents result in royalty payments, and NIH has distributed royalty income to its employees named in the

[10]SmithKline Beecham is now a part of GlaxoSmithKline.

department's Lyme disease patents. Specifically, NIH distributed a total of $7,000 to $10,000 to each of three employees working on Lyme disease from 1996 to 2000. We found no evidence that NIH employees working on Lyme disease received royalty income from patents related to Lyme disease that are not federally owned.

SGEs at NIH also reported financial interests in health sector firms. NIH provided us with 32 confidential financial disclosure forms from 32 SGEs serving on the National Advisory Allergy and Infectious Diseases Council from fiscal years 1996 through 2000. The SGEs disclosed their interests on the standard form prior to the first meeting at which they served. An abbreviated form intended to update the initial report was filed for each subsequent meeting.[11] Eighteen of the 32 SGEs reported at least 1 interest in a health sector firm on their initial financial disclosure form, and 10 of those SGEs reported more than 3 interests. We reviewed 140 abbreviated forms; a change in interests was declared on 41 of these forms from 17 of the 32 SGEs.

FDA Employees and SGEs Working on Lyme Disease

FDA employees with responsibilities for products related to the Lyme disease vaccine reported no financial interests in health sector firms that manufacture vaccines. FDA provided us with all 41 expected annual financial disclosure forms from 15 employees, covering fiscal years 1996 through 2000. One employee did report patent royalties, but the patent was unrelated to Lyme disease.

FDA employees with responsibilities for products related to the Lyme disease vaccine reported no travel payments from vaccine firms. FDA provided us with evidence of 16 cases in which FDA received travel reimbursement from nonfederal sources for travel by employees working on Lyme disease; nonprofit organizations or foreign governments provided all of these payments.

FDA SGEs did report relevant financial interests in vaccine-related firms. FDA provided us with financial disclosure forms for members of its Vaccines and Related Biologic Products Advisory Committee. It provided a form from each of the 22 SGEs serving in the 1996 meeting where a Lyme disease vaccine was discussed, and a form from each of the 21 SGEs serving in the 1998 meeting where the committee advised approval of a vaccine for Lyme disease. For the 1996 meeting, 8 of the 22 SGEs reported at least 1 interest, and 2 of those listed more than 3 financial interests. For the 1998 meeting, 13 of the 21 SGEs reported at least 1 interest on their financial disclosure form, and 6 of those SGEs reported more than 3 interests.

Potential Conflicts Have Been Waived by Agency Officials

CDC, NIH, and FDA officials reviewed the financial interests of the relevant employees and SGEs working on Lyme disease. The officials found that the interests of the employees did not constitute potential conflicts of interest. Potential conflicts of interest were identified for some SGEs, and program officials requested waivers in those cases, emphasizing the need for the person's expertise. For each request, agency officials granted waivers indicating that the need for the SGE's services outweighed the potential for a conflict of interest created by the SGE's financial interests. All three agencies indicated that they screen the financial interests of candidates for membership on the advisory committees in advance, minimizing the possibility that an SGE will have interests that cannot be waived. OGE has reviewed the

[11]The National Advisory Allergy and Infectious Diseases Council meets three times a year.

ethics programs of these agencies, including the extent to which they comply with conflict-of-interest regulations, and found them to be sound. The OGE reviews were general and did not specifically address conflicts of interest related to Lyme disease.

Centers for Disease Control and Prevention

CDC officials judged that the financial interests of employees working on Lyme disease did not pose conflicts of interest. However, CDC was not able to provide us with some of the forms we expected to receive, and some of those we did obtain contained irregularities. For the 57 employee financial disclosure forms we expected, 5 were missing and 5 lacked signatures indicating review. The 10 forms that had irregularities were from 6 employees: one employee had 2 missing forms and 1 form lacking a signature; one employee had 2 missing forms; one employee had 1 missing form and 1 form lacking a signature; and 3 other employees each had 1 form with a missing signature. The remaining 47 forms were appropriately signed, indicating that they were reviewed by agency officials. In addition, the requests for travel paid by nonfederal organizations did not indicate whether officials approved the travel before the travel date.

Agency officials judged many of the interests of SGEs serving on CDC's 1998 Advisory Committee on Immunization Practices[12] as creating potential conflicts. CDC program officials requested waivers for all of the SGEs for whom such an interest was identified, indicating the need for their services on the 1998 committee. The requests cited financial interests, some of which were identifiable as vaccine-related, and others of which were not. In addition, they acknowledged additional interests not explicitly named in the request. CDC officials signed the financial disclosure forms and indicated their agreement with the need for the SGE's services by checking a box and signing the waiver document. CDC officials signed all 12 SGE financial disclosure forms that we reviewed.

CDC officials told us that waiver requests are rarely refused because program officials screen the financial interests of potential advisors. They stated that individuals with particular vaccine-related financial interests that CDC would not consider waiving are screened out of potential membership. For example, vaccine company employees are not appointed to the Advisory Committee on Immunization Practices. The agency is in the process of revising its appointment standards to formalize this screening process with a written list of disqualifying financial interests.

During the past decade, OGE conducted two reviews of CDC's ethics procedures, in 1994 and 1999. The reviews were agencywide and not specific to the Lyme disease program. Moreover, the reviews were focused on administrative processes and did not assess the appropriateness of particular actions. In 1994, OGE commended CDC's system for reviewing and approving outside activities, the public financial disclosure system, the ethics counseling services, and the ethics education program. In spite of the generally favorable review, OGE found some specific weaknesses concerning outside activity approval, confidential financial disclosure report review, ethics training materials, and travel expense payments. In 1999, OGE concluded that CDC had made several improvements, but suggested that further improvements were necessary. For example, OGE noted, as we have in this letter, that forms were often not entirely filled out. CDC responded to OGE with evidence of the actions that it had taken to comply with the various recommendations, such as copies of its training tools and procedures.

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[12]CDC's Advisory Committee on Immunization Practices, composed of external experts, develops written recommendations for the routine administration of new vaccines, including those intended to protect against Lyme disease, to pediatric and adult populations, along with schedules regarding periodicity, dosage, and contraindications applicable to the vaccines.

National Institutes of Health

NIH officials determined that the financial interests of employees working on Lyme disease did not constitute potential conflicts of interest. NIH was not able to provide us with some of the financial disclosure forms we expected to receive, and some of the travel requests that we obtained contained irregularities. For the employee financial disclosure forms we expected, three were missing, two of which were from one employee. All 20 financial disclosure forms we obtained were signed, indicating review by agency officials. The requests for travel paid by nonfederal organizations indicated that 8 of the 45 forms were approved after the travel date. Five of the remaining forms were signed but had no approval date indicated.

Agency officials determined that many of the interests of SGEs serving on NIH's National Advisory Allergy and Infectious Diseases Council[13] could be potentially conflicting. NIH program officials requested waivers during the first year of service for all SGE members that served on the advisory committee. In addition, when abbreviated forms were filed for subsequent meetings, program officials requested a waiver when new interests were identified. The waiver requests we reviewed included health sector interests and often cited general financial interests that were not identifiable as health-related, such as personal home mortgages. NIH officials signed the financial disclosure forms and indicated that the need for the SGE's services outweighed the potential conflict of interest by checking a box and signing the waiver document, which included an explanation of the need for the services. For the SGE financial disclosure forms, NIH officials signed 31 out of 32, indicating their review of the financial interests. The remaining form was unsigned. NIH officials signed all abbreviated forms on which a change in interests was identified.

NIH officials told us that over the past 5 years, officials at the National Institute of Allergy and Infectious Diseases have not denied a waiver request for an SGE's potential conflict of interest. They also informed us that this was due to a screening process by program officials designed to eliminate those individuals who, due to their interests, would be unlikely to be granted a waiver.

During the past decade, OGE conducted two ethics reviews of NIH. The earlier review was conducted from December 1994 through March 1995 and involved the National Institute of Allergy and Infectious Diseases. The most recent review was conducted from November 1999 through March 2000 and involved the National Institute of Arthritis and Musculoskeletal and Skin Diseases. During both reviews, OGE stated that NIH administers a sound ethics program. However, OGE did make some recommendations in 1995 regarding SGEs, confidential disclosure forms, and outside activity requests. For example, it recommended that NIH ensure that ethics officials annually collect confidential financial disclosure reports from SGEs. In the 2000 report, OGE found, as we have in this letter, that waivers were often requested for all interests on the confidential financial disclosure forms, rather than being selectively requested for only those interests that would be disqualifying. In response, NIH stated that it held a training program for committee management officials to help them differentiate between interests that are potentially related to NIH work and those that are not. NIH officials said that internal ethics program reviews will now include a random review of advisory committee waivers to determine if only potentially disqualifying interests are mentioned, thereby enabling officials to assess the relevance of the requests for waivers.

[13]NIH's National Advisory Allergy and Infectious Diseases Council, composed of external experts, provides advice on the funding of grants in light of agency priorities, provides policy advice, reviews programs, and provides advice on program announcements for the National Institute of Allergy and Infectious Diseases, the institute that oversees NIH Lyme disease research.

Food and Drug Administration

FDA employees reported having no financial interests in health-related companies. The agency maintains a list of financial holdings and types of activities that are prohibited for its employees. FDA provided us with all of the forms for employees that we expected to receive. FDA officials signed all of these forms, indicating their review of financial interests. The computer printout the agency provided indicated that these employees had travel expenses paid by nonfederal organizations on 22 occasions, but this printout did not contain information about approval dates.

Prior to each of the two meetings we reviewed, agency officials determined that some of the interests of SGEs serving on FDA's Vaccines and Related Biological Products Advisory Committee[14] were potentially conflicting, given the specific topics to be discussed at each meeting. The program officials' requests for waivers referred only to those interests related to the meeting's agenda, including consideration of the Lyme disease vaccine, that met FDA's criteria for a potentially conflicting interest. Program officials did not request waivers for five SGEs with interests unrelated to the meeting topic. FDA officials granted waivers for the 12 SGE committee members serving in 1996 and 1998 for whom waivers were requested. FDA provided us with all of the SGE financial disclosure forms we expected to receive. FDA officials signed and dated all the financial disclosure forms prior to the meetings, and indicated their agreement that the need for the SGE's services outweighed the potential conflict of interest by checking a box and signing the waiver request.

FDA officials told us that very few waiver requests are denied because of an informal screening process by program officials prior to nominating individuals to serve on an advisory committee. In soliciting potential committee members, program officials inform them of the kinds of financial interests that would be disqualifying. At this stage, many potential members decide not to participate further in the process. If individuals do not disqualify themselves, then they are asked to complete the financial disclosure forms. When a potentially conflicting interest is disclosed on this form, then the program officials evaluate the need for the expertise of this individual in deciding whether to proceed to request a waiver.

In a 1997 OGE review of the FDA ethics program, OGE reported that it found the program to be efficient, effective, and in compliance with applicable statutes and regulations. OGE identified few technical and no substantive deficiencies with regard to the confidential financial disclosure system. Further, OGE specifically commended FDA's SGE and travel policies. For example, it commended officials in FDA's Office of Financial Management for ensuring that the acceptance of travel and related expenses from nonfederal sources by FDA employees is approved in advance and that payment is made either in-kind or reimbursed by check payable to the U.S. government. Due to what OGE calls "the excellent condition of the ethics program," it did not issue formal recommendations or require FDA to respond.

Agency Comments

We provided the Department of Health and Human Services the opportunity to comment on a draft of this letter. The department chose not to provide comments. The department's response is reprinted in enclosure II. However, the department did provide technical comments, which we incorporated where appropriate.

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[14]FDA's Vaccines and Related Biological Products Advisory Committee, composed of external experts, advises FDA on the licensing of vaccines, including those intended to protect against Lyme disease, by evaluating data concerning the safety, effectiveness, and use of vaccines.

Concluding Observations

There are requirements that are intended to avoid undue influence from potential conflicts of interest on federal activities and decisions. These specify that financial interests be disclosed and subsequently reviewed by relevant officials. Our review of the available evidence shows that CDC, NIH, and FDA have generally met these requirements for employees and SGEs with responsibilities related to Lyme disease. At each agency, officials are required to review the financial interests of both employees and SGEs. The practice of screening the financial interests of candidates for advisory committees prior to appointing them as an SGE may, in part, explain why agency officials granted all the program officials' requests for waivers for SGEs serving on advisory panels. The system of disclosure and review generally appears to be functioning as intended at each of these agencies.

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We will send copies of this letter to the Secretary of Health and Human Services, the Director of CDC, the Acting Director of NIH, the Acting Principal Deputy Commissioner of FDA, and others who are interested. The letter will also be available on GAO's home page at *http://www.gao.gov*. If you have questions or would like additional information, please call me at (202) 512-7250. Marcia Crosse, Donald Keller, William Hadley, and Julian Klazkin made major contributions to this letter.

Janet Heinrich
Director, Health Care–Public Health Issues
Enclosures

Financial Interest Policies

Government employees, including special government employees (SGEs), are required to disclose relevant financial interests in accordance with the Ethics in Government Act, the Office of Government Ethics (OGE) regulations, and the policies of each agency.

Employees

Employees of the executive branch may not participate in a particular government matter that has a direct and predictable effect on their financial interests. The effect does not have to be financially significant or immediate, but it does have to be directly related to the matter, and not due to speculative events, which may or may not occur and which are independent and unrelated to the matter under consideration. Financial interests include the interests of the employee, the employee's spouse or minor children, the employee's business partner, an outside organization in which the employee is involved as an employee, officer, or director, or an organization in which the employee is negotiating future employment. However, OGE regulations exempt certain financial interests. Such interests include diversified mutual funds and public securities of modest value.

Certain employees with high-level responsibilities in the executive branch are required to complete a Public Financial Disclosure Report, while less senior employees are required to file an annual Confidential Financial Disclosure Report. Federal regulations govern the information that may be requested. In accordance with those regulations, filers of the confidential financial disclosure report are required to provide descriptions, but not dollar values, of their financial interests. For the requirements of the confidential financial disclosure form, filled out by almost all of the employees whose forms we examined, see table 2.

Table 2: Reporting Requirements of the 1999 OGE Confidential Financial Disclosure Report

Section	Reporting requirements
Part I: Assets and Income	For self, spouse, and dependent children: (1) assets with a fair market value greater than $1,000 or producing greater that $200 income; and (2) sources of earned income such as fees, salaries, and honoraria over $200 ($1,000 for spouses). No earned income need be reported for dependent children.
Part II: Liabilities	For self, spouse, and dependent children: liabilities over $10,000, excluding a mortgage on the filer's personal residence.
Part III: Outside Positions	For self: any positions (employee, officer, director, or consultant), whether or not compensated, which are held during the reporting period.
Part IV: Agreements and Arrangements	For self: agreements or arrangements for current or future employment, leaves of absence, continuation of payment by a former employer, or continuing participation in an employer's benefit plan.
Part V: Gifts and Travel Reimbursements	For self, spouse, and dependent children: gifts or travel reimbursements received from one source totaling $250.

Source: OGE.

If the relevant agency official determines that one of the reported interests represents a potential conflict of interest, one of the following actions must take place. First, the employee can disqualify him(her)self from the particular matter. Second, the employee can divest him(her)self of the interest. Third, an agency's official may grant a waiver if the employee's reported financial interests are not so substantial that they would affect the integrity of the decision-making process.

Special Government Employees

An SGE is an officer or employee who is retained, designated, appointed, or employed by the government to perform temporary duties, with or without compensation, for not more than 130 days during any period of 365 consecutive days. SGEs who serve on federal advisory committees[15] make recommendations to the agencies and are subject to supervisory control. They must file an OGE Confidential Financial Disclosure Report when they are appointed. Centers for Disease Control and Prevention and National Institutes of Health SGEs complete the standard form, but OGE has granted the Food and Drug Administration (FDA) permission to substitute its own form, the FDA Confidential Financial Disclosure Report. (See table 3.)

Table 3: Reporting Requirements of the FDA Confidential Financial Disclosure Report for SGEs

Section	Reporting requirements
Investments	Firm, type of investment, owner of investment, number of shares, current value, percentage of net worth.
Employment	Firm, relationship, position in firm, date that employment or negotiations began.
Consultant / Advisor	Firm, topic/issue, amount received, dates, relation to products being discussed.
Contracts / Grants / Cooperative Research and Development Agreements	Type of agreement, product under study and indicated use, amount of remuneration to self and institution, time period, sponsor, role, awardee, relation to products being discussed.
Patents / Royalties / Trademarks	For self and firm, relation to products being discussed.
Expert Witness	Firm, issue discussed, amount received, relation to products being discussed.
Speaking / Writing	Firm, topic/issue, amount received, dates, relation to products being discussed.
Past Financial Interests	Firm, product, financial involvement, role, dates, relation to product being discussed.
Other Involvements	Identify anything that would give the appearance of a conflict, which has not been disclosed.

Source: FDA.

SGEs appointed to federal advisory committees are typically experts in their respective fields. Consequently, they may have substantial outside employment and other interests related to the subject areas for which the government desires their services. Due to the temporary nature of their appointment, it is unlikely that they would divest themselves of their long-term financial interests. A liberalized waiver provision specifically applicable to SGE's serving on federal advisory committees was enacted in 1989.[16] This provision gives the agency broad discretion to grant a waiver based on the determination that the need for an SGE's services outweighs the potential for a conflict of interest created by the financial interest involved. Waivers are requested and granted within the agencies.

[15]The Federal Advisory Committee Act (P.L. 92-463, as amended) provides the framework for the establishment of committees that can furnish expert advice, ideas, and diverse opinions to officers and agencies in the federal executive branch. Generally, the Act applies to any committee made up of at least one non-federal employee that provides advice to an agency in the executive branch.
[16]18 U.S.C. 208 (b)(3).

Enclosure II

Agency Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUN - 7 2001

Ms. Janet Heinrich
Director, Health Care--Public
Health Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Ms. Heinrich:

The Department appreciates the opportunity to comment on your draft report, "Lyme Disease: Financial Interests."

Although the Department is not providing formal comments at this time, we understand that program officials have provided your staff with extensive technical comments that may prove useful in the preparation of your final report.

Sincerely,

Michael Mangano

Michael F. Mangano
Acting Inspector General

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

(290073)